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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,668	COVACCI ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *102708*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-40,44-46,48-50,54,57,58,62,64,65 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *72* is/are allowed.

6)☒ Claim(s) *38-40,44-46,48-50,54,57,62,64,65,70 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *0* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08471491.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *120408 & 102708*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 10/27/08 has been entered.

Applicants' Amendment

2) Acknowledgment is made of Applicants' amendment filed 10/27/08 in response to the final Office Action mailed 05/29/08.

Status of Claims

3) Claims 38, 44, 49, 50, 54, 57, 64, 65, 70 and 71 have been amended via the amendment filed 10/27/08.

Claims 56, 59 and 68 have been canceled via the amendment filed 10/27/08.

Upon further consideration, the search has been extended to the polynucleotide species encoding the amino acid sequence of SEQ ID NO: 27, and claims 71 and 72 have been fully examined.

Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70-72 are under examination.

Information Disclosure Statements

4) Acknowledgment is made of Applicants' information disclosure statement filed 10/27/08 and 12/04/08. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Terminal Disclaimer

5) Acknowledgment is made of Applicants' terminal disclaimer filed 08/26/08 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 6,090,611.

Prior Citation of References

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Moot

7) The objection to the specification made in paragraph 8 of the Office Action mailed 05/29/08 is moot in light of Applicants' cancellation of claim 68.

Rejection(s) Moot

8) The rejection of claims 59 and 68 made in paragraph 10 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07 and made/maintained in paragraph 13 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is moot in light of Applicants' cancellation of the claims.

9) The provisional rejection of claims 59 and 68 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, and made/maintained in paragraph 12 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claims 56 and 68 made in paragraph 18 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claim.

11) The rejection of claims 56, 59 and 68 made in paragraph 20(d) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

12) The rejection of claims 68 and 56 made in paragraph 22 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, of record), is moot in light of Applicants' cancellation of the claims.

13) The rejection of claims 68 and 56 made in paragraph 23 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, already of record), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

14) The rejection of claims 38-40, 44, 49, 50, 62, 65 and 70 made in paragraph 10 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07 and made/maintained in paragraph 13 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is withdrawn in light of Applicants' submission of a terminal disclaimer disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of the US Patent 6,090,611.

15) The rejection of claims 44-46 made in paragraph 23 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, already of record), is withdrawn. A new rejection is set forth below to address the claims as amended.

Applicants contend that claim 44 has been amended as indicated. Applicants submit that it has not been established that the Peterson reference teaches an isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen as presently claimed. However, unlike the polynucleotide claimed in claim 38, wherein the polynucleotide is required to be all or a part of SEQ ID NO: 4, the isolated polynucleotide claimed in the amended independent claim 44 is not required to be from SEQ ID NO: 4. The only requirement of the isolated polynucleotide of claim 44 as claimed currently is that it is required to encode the EPIYA sequence, i.e., SEQ ID NO: 10. The isolated polynucleotide taught by Peterson *et al.* encodes an at least five amino acid-long polypeptide comprising the amino acid sequence of EPIYA (i.e., the instantly recited SEQ ID NO: 10). Since the prior art EPIYA sequence is structurally the same as the instantly recited SEQ ID NO: 10 encoded by the claimed polynucleotide, it is expected to necessarily serve inherently as a *H. pylori* CAI antigen immunologically identifiable with the instantly recited SEQ ID NO: 5. See the new rejection set forth below over the teachings of Peterson *et al.*

16) The rejection of claims 44 and the dependent claims 45, 46, 49, 50, 54 and 57 made in paragraph 18 of the Office Action mailed 05/29/08 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim. A new rejection is set forth below to address the claims as amended.

17) The rejection of claim 38 made in paragraph 20(a) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 48 made in paragraph 20(b) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

19) The rejection of claim 44 made in paragraph 20(c) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claims 39, 40, 44-46, 48-50, 54, 57, 58, 62, 64, 65 and 70 made in paragraph 20(d) of the Office Action mailed 05/29/08 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

Rejection(s) Maintained

21) The provisional rejection of claims 38-40, 44, 49, 50, 54, 62, 64 and 65 made in paragraph 9 of the Office Action mailed 04/09/07, made/maintained in paragraph 20 of the Office Action mailed 11/16/07, and made/maintained in paragraph 12 of the Office Action mailed 05/29/08 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is maintained for reasons set forth therein. Applicants ask that the rejection be held in abeyance pending an indication of allowable subject matter.

22) The rejection of claims 44-46, 49, 50, 54 and 57 made in paragraph 22 of the Office Action mailed 05/29/08 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, of record), is maintained for the reasons set forth therein and herein below.

Applicants contend that claim 44 has been amended as indicated. Applicants state that the claims are fully supported by Figure 4 of PCT/EP93/00472 filed 03/02/1993 and therefore the Covacci reference is not prior art to the present claims.

Applicants' argument has been fully considered, but is not persuasive. As explained in the paragraph below, instant claims continue to include new matter, and therefore are granted the effective filing date of the instant application. Therefore, the Covacci reference still qualifies as prior art.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

23) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

24) Claim 44 and the dependent claims 45, 46, 49, 50, 54 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 44, as amended, is drawn to '[a]n isolated polynucleotide encoding a *Helicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO: 10' comprises the amino acid sequence of SEQ ID NO: 10.' The dependent claims 49, 50, 54 and 57, as amended, include the similar claim language: 'polynucleotide ..... immunogenic fragment, or immunogenic derivative'. Applicants state that exemplary support for the claim is located in Figure 4 of the specification. However, unlike the polynucleotide claimed in claim 38, wherein the polynucleotide is required to be all or a part of SEQ ID NO: 4, the SEQ ID NO: 5-encoding isolated polynucleotide claimed in the amended independent claim 44 is not required to be from SEQ ID NO: 4. Therefore, the claimed polynucleotide encompasses a polynucleotide other than SEQ ID NO: 4 depicted in Figure 4 of the instant specification. As set forth previously, Figure 4 is exclusively supportive of SEQ ID NO: 4 comprising a nucleotide sequence therein that encodes the amino acid sequence of SEQ ID NO: 10,

wherein the nucleotide bases outside of the sequence that encodes SEQ ID NO: 10 are from SEQ ID NO: 4. Figure 4 is not supportive of a generic polynucleotide of any microbial or non-microbial origin comprising nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 10, but describes specifically the *cai* gene species of the G39 strain of *H. pylori* wherein the gene species is limited to SEQ ID NO: 4, but not any generic gene. New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Written Description)

25) Claims 38-40, 44-46, 48-50, 54, 57, 62, 64, 65 and 71 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

The written description requirement can be met by describing the claimed subject matter to a person skilled in the art using sufficiently detailed, relevant identifying characteristics such as functional characteristics, and correlating those functional characteristics with a disclosed structure. See *Enzo Biochem v. Gen-Probe,* 323 F.3d 956, 964, 967, 968 (Fed. Cir. 2002). Sufficient description to show possession of a genus may be achieved by means of disclosure of a representative number of polypeptides, defined by amino acid sequences falling within the scope of the genus, or recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Possession may *not* be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

In the instant application, claims 38-40, as amended, are drawn to an isolated polynucleotide comprising at least 15, 30 and 45 contiguous nucleotides respectively from the nucleotide sequence of SEQ ID NO: 4, said polynucleotide encoding a *Helicobacter pylori* CAI antigen, immunogenic fragment thereof, or immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprising the amino acid sequence of SEQ ID NO: 10. Claim 44, as amended, is drawn to an 'isolated polynucleotide encoding a H*elicobacter pylori* CAI antigen, an immunogenic fragment thereof, or an immunogenic derivative thereof which is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, wherein said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprises the amino acid sequence of SEQ ID NO: 10' comprises the amino acid sequence of SEQ ID NO: 10'. The dependent claims 49, 50, 54, 57, 64, 65 and 71, as amended, include similar claim language 'polynucleotide ..... immunogenic fragment, or immunogenic derivative'. Thus, the instant claims are drawn to a vast genus of isolated polynucleotide species including the derivative species of SEQ ID NO: 4, encoding the polypeptide derivative species that are required to have the intended function(s). The variations within the encompassed genus are huge. The at least five-, ten-, or 15-mer polypeptide derivatives do not exist independent of their function, but are required to have the capacity to be immunologically identifiable with the amino acid sequence of SEQ ID NO: 5. The polypeptide derivative species encoded by the claimed polynucleotide have specific biological properties dictated by the structure of the polypeptide derivatives and the corresponding structure of the structural gene sequences which encode the derivatives. A representative number of isolated polynucleotide species encoding representative number of immunogenic five-mer, ten-mer, or a fifteen-mer polypeptide derivatives that retain the immunologic identifiability with the amino acid sequence of SEQ ID NO: 5 is not described. This is important because the retention of immunogenicity and immunologic identifiability with the amino acid sequence of SEQ ID NO: 5 is not predictable given the art known conformational complexity of polypeptide epitopes. This is

also critical given the antigenic variability or heterogeneity among the polypeptides produced by *H. pylori*. The specification intends therapeutic, prophylactic (vaccine) and diagnostic applications for the immunogenic derivatives encoded by the claimed polynucleotide products. Diagnostic or vaccine applications minimally require an ability to elicit a specific immune response or bind specifically to a specific antibody. The precise structure or relevant identifying characteristics of a representative number of isolated polynucleotide species that encode a representative number of immunogenic derivatives immunologically identifiable with the amino acid sequence of SEQ ID NO: 5 are not adequately described. Regardless of the complexity or simplicity of the method of isolation and method of testing, conception cannot be achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is a part of the invention and a reference to a potential method of isolating or testing it. It does not appear that Applicants were in possession of the claimed product, wherein the product is required to possess the specific functions recited in the claims. For example, Applicants were not in possession of an isolated 15 nucleotide-long polynucleotide encoding an immunogenic derivative of SEQ ID NO: 10 wherein the derivative is immunologically identifiable with the amino acid sequence of SEQ ID NO: 5. In order to be immunologically identifiable with the amino acid sequence of SEQ ID NO: 5, the encoded polypeptide derivative must be unique or specific to the *Helicobacter pylori* CAI antigen of SEQ ID NO: 5 and must not be shared by other microbial or non-microbial antigens. A review of the specification shows that Applicants have not described isolated polynucleotide species that encode polypeptide derivative species of such specificity or immunological identifiability. The state of the art, for example, indicates that an at least five amino acid-long fragment of the instantly recited SEQ ID NO: 5, EPYIA, is not specific or unique to *Helicobacter pylori* CAI antigen, but is shared by non-*Helicobacter pylori* CAI antigens, for example, by a human general transcription factor IIE (see Figure 1 of Peterson *et al. Nature* 354: 369-373, 1991, of record) and a *Drosophila* catalase (see the amino acid sequence on page 3663 of Orr *et al. Nucleic Acid Res.* 18: page 3663, 1990). Similarly, six contiguous asparagine residues within the SEQ ID NO: 5 are ubiquitously comprised in several non-*Helicobacter pylori* polypeptides, including the commercially available polyasparagines. This means that the epitopes of *Helicobacter pylori* CAI antigen, SEQ ID NO: 5 in particular, are not specific to *Helicobacter pylori*, but are immunologically identifiable with non-*Helicobacter pylori* polypeptides. Given this

immunologic/epitopic non-specificity and the conformational complexity of polypeptide epitopes, one of skill in the art cannot envisage the precise structure or relevant identifying characteristics of immunologically identifiable at least five-mer, ten-mer or 15-mer CAI antigen derivatives that are *Helicobacter pylori* CAI-specific or SEQ ID NO: 5-specific, without adequate written description. In view of the level of knowledge and skill in the art, the art-disclosed epitopic non-specificity, and the art-recognized functional unpredictability, one of skill in the art would not recognize from the instant disclosure that Applicants were in possession of the recited CAI polypeptide derivatives having the recited size and properties. See *Written Description Requirement* published in *Federal Register*, Vol. 66, No. 4, Friday, 05 January 2001, Notices, p. 1099-1111.

There has to be some nexus between the structure of the polypeptide derivative sequence and the function of such a derivative. However, the function cannot be predicted from the modification or derivatization of the structure of the recited derivative of SEQ ID NO: 5. Applicants have not shown that modification or derivatization of the polypeptide of SEQ ID NO: 5 to a five-mer, ten-mer or fifteen-mer size would automatically predict the production of polypeptide derivatives of *H. pylori* CAI antigen having the required functions. Applicants have not described which of SEQ ID NO: 5's or SEQ ID NO: 10's amino acids can be varied such that the polypeptide derivative still maintains the immunological idenfiability with SEQ ID NO: 5 and *H. pylori* CAI antigen specificity such that they can be of diagnostic, prophylactic and therapeutic significance, is not adequately described. *Vas-Cath Inc. V. Mathukar, 19 USPQ2d 1111* states that Applicant "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, is for purposes of the 'written description' inquiry, whatever is now claimed." See page 1117. With respect to the written description requirement, while 'examples explicitly covering the full scope of the claim language' typically will not be required, a sufficient number of representative species must be included 'to demonstrate that the patentee possesses the full scope of the [claimed] invention'. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). In the instant case, Applicants' specification does not contain a written description sufficient to show they had possession of the full scope of the claimed invention at the time the application was filed. Clearly, Applicants did not describe the invention of the instant claims sufficiently to show that they had possession of the claimed genus of polynucleotides. See e.g., *Noelle v. Lederman*, 355 F.3d 1343,

1348, 69 USPQ2d 1508, 1513 (Fed. Cir. 2004) ('invention is, for purposes of the written description inquiry, *whatever is now claimed*'). Without a correlation between structure and function, the claims do little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. Appl. & Int. 2007) citing *Eli Lilly*, 119 F.3d at 1568, 43 USPQ at 1406 ('definition by function ..... does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is'). The instant claims are viewed as not meeting the written description provision of 35 U.S.C. § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

26) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

27) Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention.

(a) Claims 38, 44, 49, 50, 54, 57, 64, 65, 70 and 71 are vague and indefinite in the use of the abbreviated language 'CAI' in the claim. It is suggested that the abbreviation be recited as a full terminology at first occurrence in the base claim, with its abbreviated recitation retained in parentheses.

(b) Claims 38, 44, 49, 50, 54, 57, 64, 65 and 71 are vague and indefinite in the limitation 'derivative ... immunologically identifiable with ... SEQ ID NO: 5', because it is unclear what is encompassed in this limitation. What constitutes such a derivative, and how much of the CAI antigen's original structure has to be retained such that the resulting antigen can be considered a 'derivative ... immunologically identifiable with ... SEQ ID NO: 5' is not clear. What does 'immunological identifiability with .... SEQ ID NO: 5' involve is unclear. The metes and bounds of the structure encompassed in the above-identified are indeterminate.

(c) Claims 38 and 44 are indefinite because these claims lack proper antecedent basis in the limitations: 'immunogenic fragment' and 'immunogenic derivative'. See lines 5 and 6 of claim 38 and line 4 of claim 44. For proper antecedent basis, it is suggested that Applicants replace he above-identified limitations with the limitations: --said immunogenic fragment-- and --said immunogenic derivative--.

(d) Claims 49, 50, 54, 57, 64, 65 and 71 are indefinite because these claims lack proper antecedent basis in the limitations: 'immunogenic fragment' and 'immunogenic derivative'. See line 2. For proper antecedent basis, it is suggested that Applicants replace he above-identified limitations with the limitations: --said immunogenic fragment-- and --said immunogenic derivative--.

(e) Claim 54, which depends from claim 44, is indefinite and confusing in the limitation: 'said *Helicobacter pylori* CAI antigen, immunogenic fragment, or immunogenic derivative comprising amino acids 1-1147 of the amino acid sequence of SEQ ID NO: 5'. The amino acids 1-1147 of the amino acid sequence of SEQ ID NO: 5 represent the full length CAI antigen of the single *Helicobacter pylori* CAI antigen species of the instant invention. See Figure 4. It is unclear how the 1147 amino acid-long, full length SEQ ID NO: 5 can be comprised within an immunogenic fragment or an immunogenic derivative.

(f) Claims 39, 40, 48, 58, 62, 64, 65, 70 and 71, which depend directly or indirectly from claim 38, and claims 45, 46, 49, 50, 54 and 57, which depend directly or indirectly from claim 44, are rejected as being indefinite, because of the indefiniteness or vagueness, identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

28) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

29) Claims 44-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, of record) as evidenced by Stein *et al.* (*Mol. Microbiol.* 43: 971-980, 2002 – Applicants' IDS).

Peterson *et al.* taught an isolated polynucleotide encoding an at least five amino acid-long polypeptide comprising the amino acid sequence of EPIYA (i.e., the instantly recited SEQ ID NO: 10) and *E. coli* cells overexpressing the same. See right column of page 369 and Figure 1. Since the prior art EPIYA sequence is structurally the same as the instantly recited SEQ ID NO:

10 encoded by the claimed polynucleotide, it is expected to necessarily serve inherently as a *H. pylori* CAI antigen immunologically identifiable with the instantly recited SEQ ID NO: 5. That the prior art EPIYA sequence is the same the Applicants' *H. pylori* CAI antigen, EPIYA or SEQ ID NO: 10, is inherent from the teachings of Peterson *et al.* in light of what is well known in the art. For example, Stein *et al.* illustrate that EPIYA motif is an essential part of the CagA protein of *H. pylori.* See title and abstract of Stein *et al.*

Claims 44-46 are anticipated by Peterson *et al.* The reference of Stein *et al.* is **not** used as a secondary reference in combination with Peterson *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Peterson *et al.* with the unrecited limitation(s) being inherent in view of what is known in the art as explained above. See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

30) Claims 38-40, 44-46, 48-50, 54, 57, 58, 62, 64, 65, 70 and 71 stand rejected. Claim 72 is allowable.

31) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

32) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

33) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2009